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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/963,959	09/25/2001	Rachel E. Meyers	10448-095001	1570

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Louis Myers
Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804

EXAMINER	
SAKELARIS, SALLY A	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/963,959	Applicant(s) MEYERS, RACHEL E.	
	Examiner Sally A Sakelaris	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/3/1999* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims 1-4, 8 and 13 are drawn to polynucleotides, vectors, host cells and methods for expression of polypeptides, and a kit comprising a nucleic acid probe or primer classified in Class 435, subclasses 69.1, 252.3, and 320.1, Class 536, subclass 23.5, 24.31 and 24.33 and Class 536 subclass 23.1, 24.33, and 24.3

II. Claims 5 and 6 are drawn to polypeptides, classified in Class 530, subclass 350.

III. Claim 7 is drawn to an antibody, classified in Class 530, subclass 387.

IV. Claim 9 is drawn to a method of detecting a polypeptide as classified in Class 435, subclass 7.1

V. Claim 10 is drawn to a kit comprising a compound that selectively binds to a polypeptide as classified in Class 514, subclass 2; further classification cannot be determined without additional information as to the structure of the compound.

VI. Claims 11 and 12 are drawn to a method of detecting the presence of a nucleic acid as classified in Class 435, subclass 6.

VII. Claim 14 is drawn to a method for identifying a binding partner to a polypeptide, classified in Class 435, subclass 7.1

VIII. Claim 15 is drawn to a method for modulating the activity of a polypeptide as classified in Class 435, subclass 4.

IX. Claims 16-18 are drawn to a method of inhibiting aberrant activity of a 33521-expressing cell using a polypeptide as classfied in Class 435, subclass 7.1.

X. Claims 19 and 20 are drawn to a method of treating or preventing a disorder by aberrant activity of a 33521-expressing cell of a nucleic acid as classified in Class 514, subclass 44.

2. The inventions are distinct, each from the other because of the following reasons:

a. Inventions I and II are patentably distinct in structure and physiochemical properties. Invention I is drawn to nucleic acids whereas invention II is drawn to proteins. Because nucleic acids are composed of nucleotides and proteins are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while the proteins may be utilized in ligand binding assays or to generate antibodies. The protein of invention II does not require the particular products of the nucleic acids of group I since the proteins of invention II can be isolated from natural sources or chemically synthesized.

b. Inventions I and III are patentably distinct in structure and physiochemical properties. Invention I is drawn to nucleic acids whereas invention III is drawn to antibodies. Because nucleic acids are composed of nucleotides and antibodies are composed of amino acids, the inventions have different structural and functional properties. Furthermore, the compositions are utilized in different methodologies, such that nucleic acids may be utilized in hybridization assays, while the antibodies may be utilized in assays to detect the presence or absence of a protein. The nucleic acids of invention I are not required to obtain the antibodies of invention III.

c. Inventions I and VI and I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of invention I can be used in a materially different processes such as for sequencing reagents and involving amplification and sequencing methods in order to achieve the objective of genotyping an individual for pedigree analysis.

d. Inventions I and IV, I and VII, I and VIII, and inventions I and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the nucleic acids of invention I are not required to practice the methods of invention IV, VII, VIII and IX involving polypeptides.

e. Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the nucleic acids of invention I are not required for the kit of group V involving polypeptides.

f. Inventions II and III are patentably distinct in structure and physiochemical properties. Invention II is drawn to polypeptides whereas invention III is drawn to antibodies. The polypeptide of Group II is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group III is also composed of

amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. The products of inventions II and III are utilized in materially different processes such that the proteins of invention II may be used to make a fusion protein while the antibodies of invention III may be used in an immunoassay. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups II, and III are patentably distinct from each other.

g. Inventions II and IV, II and VII, II and VIII and inventions II and IX are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention II can be used in a materially different process such as for determining the protein's folding conformation and the resulting crystal structure or for generating antibodies.

h. Inventions II and VI, and inventions II and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the polypeptides of invention II are not required to practice the methods of inventions VI and X involving polynucleotides.

i. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention II can be used in a materially different processes such as for determining the protein's folding conformation and the resulting crystal structure.

j. Inventions III and IV, III and VI, III and VII, III and VIII, III and IX, and inventions III and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the antibody of invention III is not required to practice the methods of inventions IV, VI, VII, VIII, IX and X involving polynucleotides and polypeptides.

k. Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of use together because the antibody of invention III is not included in the kit of inventions V involving polypeptides.

l. The methods of inventions IV, VI, VII, VIII, IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have

different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to materially distinct methods, which require the use of different reagents, have different process steps and have distinct objectives. The method of invention IV includes steps involving the detection of a polypeptide. Invention VI includes a method for detecting the presence of a nucleic acid. The method of invention VII involves the necessary steps for identifying a binding partner of a polypeptide. Invention VIII includes steps necessary for the modulation of expression for a polypeptide. Invention IX includes a method that involves the steps of inhibiting aberrant activity of an expressing 33521 cell. In the instant case the different aforementioned inventions all have different functions and are not disclosed as capable of use together.

3. Because these invention are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-X require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantai Dessau whose telephone number is (703)605-1237.

Sally Sakelaris
6/18/02

CARLA J. MYERS
PRIMARY EXAMINER